

## Patent Claims

1. Use of carbamoyl phosphate synthetase (CPS 1) and its fragments as a marker substance for the diagnosis and for the prognosis and monitoring of inflammations and infections and for diagnosis, monitoring and prognosis of liver failure in the case of multiorgan failure or for determination in connection with inflammatory liver diseases.  
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2. Use of amino acid sequences of the N-terminal part of carbamoyl phosphate synthetase (CPS 1; SEQ ID NO:6) as marker peptides for the diagnosis and the prognosis and the monitoring of inflammations and infections.  
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3. Use of CPS 1 or CPS 1 fragments according to Claim 2 in early differential diagnosis and detection for the prognosis, the assessment of the severity and the therapy-accompanying monitoring of sepsis and severe infections, in particular sepsis-like systemic infections, by determination of the occurrence and/or of the amount of soluble CPS 1 fragments in a biological fluid of a patient.  
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4. Use of CPS 1 according to Claim 1 in the early differential diagnosis and detection for the prognosis, the assessment of the severity and the therapy-accompanying monitoring of sepsis and severe infections, in particular sepsis-like systemic infections, by determination of the occurrence and/or the amount of CPS 1 in a biological fluid of a patient.  
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5. Use according to either of Claims 2 and 3 of CPS 1  
fragments which correspond to a sequence of at  
least 6 amino acids from the N-terminal part of  
the CPS 1 sequence, comprising the amino acids 1  
5 to about 630 of the complete CPS 1 sequence  
(SEQ ID NO:6).
10. 6. Use according to either of Claims 1 and 2,  
characterized in that the CPS 1 fragments are  
selected from fragments having a molar mass,  
determined by gel electrophoresis, of from 68 to  
70 kDa  $\pm$  3 kDa and isoelectric points in a range  
from 5.5 to 6.1.
15. 7. Method for the early differential diagnosis and  
detection, for the prognosis and the assessment of  
the severity and for the therapy-accompanying  
monitoring of sepsis and severe infections, in  
particular sepsis-like systemic infections,  
20. characterized in that the presence and/or amount  
of CPS 1 and/or CPS 1 fragments from the N-  
terminal part of CPS 1 in a biological fluid of a  
patient is determined, and conclusions are drawn  
with respect to the presence, the expected course,  
25. the severity or the success of a therapy of a  
sepsis or infection from the detection and/or the  
amount of CPS 1 or at least one of the specific  
fragments.
30. 8. Method according to Claim 7, characterized in that  
the CPS 1 sequences used for the determination are  
sequences of fragments from an N-terminal part of  
CPS 1, comprising the amino acids 1 to about 630

of the complete CPS 1 sequence (SEQ ID NO:6).

9. Method according to Claim 7 or 8, characterized in that the specific CPS 1 immunoreactivity can be assigned to plasma components having a molar mass, determined by gel electrophoresis, of 200 kDa  $\pm$  50 kDa and/or components having a molar mass of from 68 to 70 kDa  $\pm$  3 kDa and isoelectric points in a range from 5.5 to 6.1.
10. Method according to any of Claims 7 to 9, characterized in that the specific CPS 1 fragments, or the fragments used for assay purposes, are those fragments which contain at least 2 amino acid partial sequences according to SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4 and/or SEQ ID NO:5, SEQ ID NO:7 or SEQ ID NO:8.
11. Method according to any of Claims 7 to 10, characterized in that it is an immunodiagnostic assay method.
12. Method according to any of Claims 7 to 10, characterized in that the determination of the soluble CPS 1 or of the CPS 1 fragments is carried out indirectly as a determination of an associated CPS 1 mRNA or as a determination of the CPS 1 enzyme activity.
- 30 13. Method according to any of Claims 7 to 12, characterized in that it is carried out as part of a multiparameter determination, in which at least one further sepsis parameter is simultaneously

determined and a measured result in the form of a set of at least two measured quantities is obtained and is evaluated for the fine diagnosis of sepsis.

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14. Method according to Claim 13, characterized in that, in addition to at least one CPS 1 fragment, at least one further parameter which is selected from the group consisting of procalcitonin, CA 19-9, CA 125, S100B, S100A proteins, soluble cytokeratin fragments, in particular CYFRA 21, TPS and/or soluble cytokeratin-1 fragments (sCY1F), the peptides inflammin, CHP and LASP-1 and peptide prohormone immunoreactivity and the C-reactive protein (CRP) is determined as part of the multiparameter determination.
15. Method according to Claim 13 or 14, characterized in that the multiparameter determination is carried out as a simultaneous determination by means of a chip technology measuring apparatus or of an immunochromatographic measuring apparatus.
16. Method according to Claim 15, characterized in that the evaluation of the complex measured result obtained using the measuring apparatus is effected with the aid of a computer program.
17. Use of CPS 1 inhibitors for the preparation of medicaments for the treatment of sepsis and severe liver diseases.

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